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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 98N–0087]

General Hospital and Personal Use Devices: Classification of the Apgar Timer, Lice Removal Kit, and Infusion Stand

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Apgar timer, the lice removal kit, and the infusion stand into class I (general controls) based on new information regarding these devices. FDA is also exempting the devices from the requirement of premarket notification and is exempting the Apgar timer from most of the requirements of the good manufacturing practice regulations. This action is taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: (*Insert date 30 days after date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Patricia M. Cricenti, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 10, 1998 (63 FR 11632), FDA issued a proposed rule to classify the Apgar timer, the lice removal kit, and the infusion stand into class I (general controls) and to exempt them from premarket notification procedures based on new information regarding these devices. FDA also proposed to exempt the Apgar timer from the current good manufacturing practice requirements in part 820 (21 CFR part 820), with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons were given until June 8, 1998, to comment on the proposed rule. FDA did not receive any comments on the proposed rule.

II. FDA's Conclusion

FDA has concluded that the Apgar timer, the lice removal kit, and the infusion stand do not present unreasonable risks to the public health and that general controls would provide reasonable assurance of the safety and effectiveness of the devices. On November 21, 1997, the President signed FDAMA into law. Section 206 of FDAMA, in part, added a new section 510(l) to the act (21 U.S.C. 360(l)). Under section 501 of FDAMA, new section 510(l) became effective on February 19, 1998. New section 510(l) provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury (hereinafter referred to as ''reserved criteria''). FDA has determined that these devices do not meet the reserved criteria and, therefore, they are exempt from the premarket notification requirements. FDA is finalizing the classification of these devices, the exemptions from premarket notification for all of the devices, and the exemption from the good manufacturing practices requirements for the Apgar timer.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. For these three devices, FDA is classifying them into class I, the lowest level of control allowed. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 880.2930 is added to subpart C to read as follows:

§ 880.2930 Apgar timer.

(a) *Identification.* The Apgar timer is a device intended to alert a health care provider to take the Apgar score of a newborn infant.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

3. Section 880.5960 is added to subpart F to read as follows:

§ 880.5960 Lice removal kit.

(a) *Identification.* The lice removal kit is a comb or comb-like device intended to remove and/or kill lice and nits from head and body hair. It may or may not be battery operated.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

4. Section 880.6990 is added to subpart G to read as follows:

§ 880.6990 Infusion stand.

(a) *Identification.* The infusion stand is a stationary or movable stand intended to hold infusion liquids, infusion accessories, and other medical devices.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

Dated: 9-16-98
September 16, 1998

D.B. Burlington
Director
Center for Devices and Radiological Health

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